K101995

JAN 11 2011

510(k) Summary of Safety and Effectiveness Information

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

(This section is not confidential)

DATE THIS SUMMARY WAS PREPARED

July 16st, 2010

SUBMITTER'S NAME AND ESTABLISHMENT ADDRESS:

Oridion Capnography Inc.
160 Gould Street
Needham, MA 02494

ESTABLISHMENT REGISTRATION NUMBER

3003941644

CONTACT PERSON:

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DEVICE INFORMATION

Trade Name: Capnostream20p with Masimo MX1 SpO2 board.
Common Name: Two Parameter Bedside Monitor
Classification Name: Capnograph/Pulse Oximeter
Regulation Number:
868.1400, Carbon Dioxide Analyzer (Classification CCK)
870.2700 Pulse Oximeter (Classification DQA)
Device Listing Number:

PREDICATE DEVICE

Capnostream$_{20\,p}$ with SET parameters is substantially equivalent to the following commercially available devices:

Manufacturer	Device	510(k) No.	Clearance Date
Oridion 1987 Medical Ltd	Capnostream20	K094012	February 9, 2010
Masimo Corporation	Masimo Rainbow SET Radical 7 Pulse CO-Oximeter	K080238	May 12, 2008

DEVICE DESCRIPTION

The Capnostream20p bedside monitor is a two parameter monitor consisting of a microMediCO2 capnography module and/or a pulse oximetry module implemented in a host device. The host device displays parameters received from the respective modules and generates alarms when preset alarm thresholds are crossed. The device is classified as CCK Class II according to 21 CFR § 868.1400 - Carbon Dioxide Analyzer with DQA 21 CFR § 870.2700 Pulse Oximeter listed as an additional or alternate classification.

This device has two modules that are classified as follows:

- 21 CFR 868.1400, Carbon Dioxide Analyzer (Classification CCK)
- 21 CFR 870.2700 Pulse Oximeter (Classification DQA).

Each module is controlled by dedicated software that is an integral part of the respective module. Each module provides parameters to the host software (the Capnostream20p device software) which then controls the display of the received parameter values and creates alarms when the values cross the preset thresholds.

The microMediCO2 module provides the following inputs to the host monitor:

FiCO2, EtCO2 numeric, EtCO2 waveform, Respiratory Rate, IPI (Integrated Pulmonary Index).

The Masimo MX1 SpO2 module, integrated in the Capnostream20 p monitor presented in this submission, provides the following parameters to the host for display: SpO2 (functional oxygen saturation of arterial hemoglobin), pulse rate, SpCO (carboxyhemoglobin saturation in blood), SpMet (methemoglobin saturation in blood) and SpHb (total hemoglobin concentration in blood).

The host monitor will display this data to the user in numerics via a screen, and will also display the CO_2 waveform and SpO_2 (pleth) waveform or pulse bar graph.

The three measurements will be available both real time and in trend summaries.

In addition, the MX1 board provides a Perfusion Index (PI) indicating the relative pulsatile strength at the sampling site is provided to the host monitor for display.

The host displays the Rainbow SET parameters values on the screen alongside the four IPI (Integrated Pulmonary Index) parameters and the IPI value as presented on the predicate device.

INTENDED USE

The Capnostream®20p combined capnograph/pulse oximeter monitor and its accessories are intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and with continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is also indicated for continuous non-invasive monitoring of carboxyhemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), methemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor) and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). It is intended for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport and home environments.

The Capnostream®20p monitor provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10,

where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.

The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.

COMPARISON TO PREDICATE DEVICES

The Capnostream20p with Masimo MX1 board is equivalent to the predicate Capnostream20 with microMediCO2 CO2 board with the exception of the addition of the three Rainbow SET parameters (SpCO, SpMET and SpHb).

The new device meets the safety and performance standards met by the predicate devices.

Software testing was performed to validate the performance of the new monitor software and its substantial equivalence to the predicate device. The functional features and the intended use of Capnostream20p with Masimo MX1 board are substantially equivalent to the predicate devices.

A hazard analysis was carried out on the Capnostream host monitor displaying the Rainbow SET values. This hazard analysis concluded that any residual risks were judged as acceptable when weighed against the intended benefits of use of the system.

Attribute	**Capnostream20p with Masimo MX1 SpO2 board, software version 6.1.**	**Predicate Device: Capnostream Bedside Monitor with microMediCO$_2$: K094012, software version 5.6**
Indications for use	The Capnostream®20p combined capnograph/pulse oximeter monitor and its accessories are intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and with continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin	The Capnostream®20p combined capnograph/pulse oximeter monitor is intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and with continuous non-invasive monitoring of functional oxygen

	(SpO2) and pulse rate. It is also indicated for continuous non-invasive monitoring of carboxyhemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), methemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor) and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). It is intended for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport and home environments. The Capnostream®20p monitor provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status. The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.	saturation of arterial hemoglobin (SpO2) and pulse rate. It is intended for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport and home environments. The Capnostream®20p monitor provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status. The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.

Target population	Identical	It is intended for use with neonatal, pediatric, and adult patients
Design	Equivalent to the Capnostream20 described in K094012	See K094012.
Where Used	It is to be used by physicians, nurses and other trained health care providers in critical care patient settings, such as anesthesiology, intensive care medicine, neonatal intensive care and other health care areas.	It is to be used by physicians, nurses and other trained health care providers in critical care patient settings, such as anesthesiology, intensive care medicine, neonatal intensive care and other health care areas.
Performance Standards	ISO 21647 ISO 9919	ISO 21647 ISO 9919
Safety Standards	IEC/EN 60601-1 IEC/EN 60601-1-2 IEC 60601-1-8 ISO 14971 EN 980	IEC/EN 60601-1 IEC/EN 60601-1-2 IEC 60601-1-8 UL 60601-1 ISO 14971 EN 980
Biocompatibility	There are no issues of biocompatibility for this device and no biocompatibility testing was performed.	There are no issues of biocompatibility for this device and no biocompatibility testing was performed.
Sterility	This device does not require sterilization	This device does not require sterilization

The Capnostream20p with Masimo MX1 SpO2 board enables the measurement of three additional parameters, which are available in the predicate device MASIMO RAINBOW SET RADICAL 7 PULSE CO-OXIMETER (K080238):

- SpCO: carboxyhemoglobin saturation in blood
- SpMet: methemoglobin saturation in blood
- SpHb: total hemoglobin concentration in blood

These parameters have been clinically validated by Masimo Corporation.

CONCLUSION

Capnostream20p with Masimo MX1 SpO2 board functionality does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

Therefore, the device is substantially equivalent to the predicate devices with respect to safety, effectiveness, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Rachel Weissbrod
Director of Regulatory Affairs
Oridion Capnography, Incorporated
160 Gould Street
Needham Heights, Massachusetts 02494

JAN 11 2011

Re: K101995
Trade/Device Name: Capnostream20p
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, CCK76
Dated: January 4, 2011
Received: January 7, 2011

Dear Ms. Weissbrod:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JAN 1 1 2011

Statement of Indications for Use

CAPNOSTREAM®20p with Masimo MX1 SpO2 Board
(This document is not confidential)

Indications for Use

November 24, 2010

510(k) Number (if known): K101995

Device Name: Capnostream20p

Indications for Use:

The Capnostream®20p combined capnograph/pulse oximeter monitor and its accessories are intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and with continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is also indicated for continuous non-invasive monitoring of carboxyhemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), methemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor) and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). It is intended for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport and home environments.

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The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Oridion Medical 1987 Ltd.

510(k) Number: K101995